recognize this specific problem. We are deeply worried that we are not the only ones to observe this sad experience: A case reported in Germany led to an unusual procedure and finally resulted in a transplant.[7,8] Another similar observation was made in the United States after implantation of the device and led to correspondence with us: ''I read with great interest your report of 7 patients with bad outcomes after placement of the Shelhigh stentless valve-conduit. We have had recent experience with a man who experienced valve failure 3 years after placement of one Shelhigh conduit. A false aneurysm and extensive inflammation were found at surgery (the surgeon said he thought there may be an abscess), and the entire prosthesis had to be removed and replaced with a homograft. Cultures for bacteria only were negative. The patient did well postoperatively and was discharged on day 17 postoperatively. Our pathologists also analyzed the tissue and found extensive acute and chronic inflammation. On special staining, the wall of the conduit was infiltrated with numerous acid fast bacteria. Unfortunately, we did not culture for acid fast organisms so we were not be able to identify what it is.'' (P. O'Keefe, Loyola University Medical Center, personal communication).

We urge Dr Gabbay not to fight against reports regarding the NR-2000C but to encourage him to shed light on those cases and to recognize that we had made several attempts to warn him not only about the aortic valved conduit but also about several other devices that we found to give unsatisfactory results (e.g. the pulmonary conduit and the bovine IMA).

Thierry Carrel, MD[a]
Florian S. Schoenhoff, MD[a]
Friedrich Eckstein, MD[b]
Jürg Schmidli, MD[a]
Department of Cardiovascular Surgery, University Hospital Berne[a]
Berne, Switzerland

Department of Cardiac Surgery
University of Basel[b]
Basel, Switzerland

References

1. Carrel T, Schoenhoff F, Schmidli, Stalder M, Eckstein F, Englberger L. Deleterious outcome of No-React-treated stentless valved conduits after aortic root replacement: why were warnings ignored? *J Thorac Cardiovasc Surg*. 2008;136:52-7. Epub 2008 May 27.
2. Krähenbühl ES, Immer FF, Stalder M, Englberger L, Eckstein FS, Schmidli J, et al. Technical advances improved outcome in patients undergoing surgery of the ascending aorta and/or aortic arch: ten years experience. *Eur J Cardiothorac Surg*. 2008;34:595-9.
3. Immer FF, Moser B, Krähenbühl ES, Englberger L, Stalder M, Eckstein FS, et al. Arterial access through the right subclavian artery in surgery of the aortic arch improves neurologic outcome and mid-term quality of life. *Ann Thorac Surg*. 2008; 85:1614-8.
4. Stalder M, Staffelbach S, Immer FF, Englberger L, Berdat PA, Eckstein FS, et al. Aortic root replacement does not affect outcome and quality of life. *Ann Thorac Surg*. 2007;84:775-80.
5. Warning letter from FDA, April 26, 2000. Available at: http://www.fda.gov/foi/warning_letters/archive/m3695n.pdf. Accessed September 8, 2008.
6. Letter from FDA, May 2, 2007. Available at: http://www.fda.gov/ora/frequent/483s/shelhigh/requested_recall_shellhigh_20070504.pdf. Accessed September 8, 2008.
7. Carrel TP. Another disastrous outcome following aortic root replacement with the Shelhigh No-react aortic valved tube. *Thorac Cardiovasc Surg*. 2008;56:314-5.
8. Tjan TD, Klotz S, Schmid C, Scheld HH. Creation of a self-made total artificial heart using combined components of available ventricular assist devices. *Thorac Cardiovasc Surg*. 2008;56:51-3.

doi:10.1016/j.jtcvs.2008.10.019

SHELHIGH BIOPROSTHESIS IN ACTIVE INFECTIVE ENDOCARDITIS

To the Editor:

A recent article by Carrel and colleagues[1] deals with the deleterious outcome of patients who received No-React (Shelhigh, Inc, Union, NJ)–treated stentless valved conduits. Seven (6.1%) of 115 patients presented with sudden disastrous findings at the level of the aortic root, and 4 of them underwent emergency operations because of disintegration of the graft along with rupture of the aortic root. The authors reported that retrospectively the main findings were persistent fever or subfebrility over months. They conclude that the use of the Shelhigh aortic stentless prosthesis can no longer be advocated. Is it possible that the authors have overlooked the patients' clinical condition of persisting postoperative fever, which can lead to the severe prosthetic endocarditis described in their article?

We previously reported very good clinical results from our center using the above products, especially in patients with severe active infective endocarditis. The device was tested with satisfactory results, and preliminary follow-up data were published in 2003 and 2005.[2,3] Recent publications in 2006 and 2008 have shown satisfactory early and midterm results with a low reinfection rate in patients with native or prosthetic endocarditis complicated by paravalvular abscess, and the hemodynamic function of the implants in the aortic position was comparable with that of homografts.[4,5] These articles have perhaps been overlooked by Carrel and colleagues.

From February 2000 until July 2008, 319 Shelhigh No-React–treated stentless valves have been implanted in 305 patients in our institution. Of these, 17 (5.5%) patients required reoperations because of reinfection. The 30-day and 1-, 3-, and 5-year rates for freedom from reoperation caused by reinfection were 100%, 94.4% ± 1.8%, 87.0% ± 3.2%, and 83.8% ± 4.4%, respectively.[4]

Analysis of reoperation because of valve-related complications showed 12 patients who underwent reoperations because of paravalvular leakage, which is mainly related to endocarditis. The freedom from reoperation because of valve-related complications is shown in Figure 1: the 30-day and 1- and 5-year freedom from reoperation rates were 98.9% ± 0.7%, 97.9% ± 8.4%, and 92.3% ± 2.3%, respectively.

Thus, in our series, there was no patient who required reoperation, as

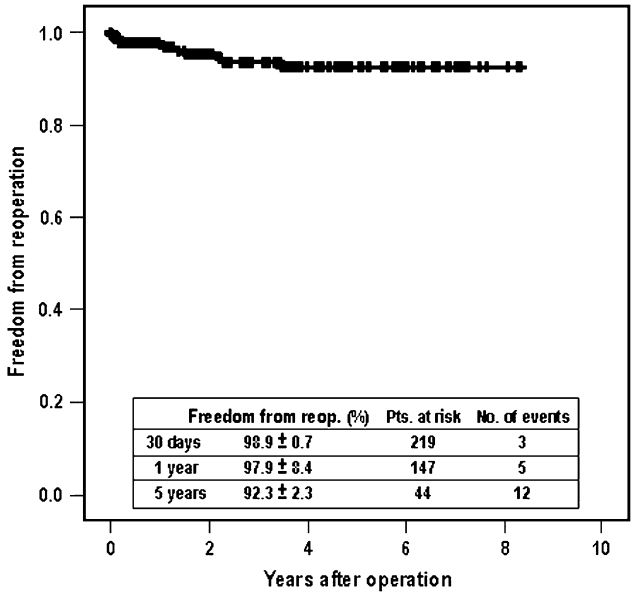

FIGURE 1. Freedom from reoperation because of valve-related events after Shelhigh implantation (n = 305 patients): Deutsches Herzzentrum Berlin, February 2000 to July 2008.

described in the article by Carrel and colleagues.[1] In contrast, we were able to document good outcomes of the treated patients and did not find that the Shelhigh products were associated with ''deleterious outcome.''

Michele Musci, MD
Henryk Siniawski, MD, PhD
Roland Hetzer, MD, PhD
Department of Cardiothoracic and Vascular Surgery
Deutsches Herzzentrum Berlin
Berlin, Germany

References

1. Carrel TP, Schoenhoff FS, Schmidli J, Stalder M, Eckstein FS, Englberger L. Deleterious outcome of No-React–treated stentless valved conduits after aortic root replacement: why were warnings ignored? *J Thorac Cardiovasc Surg*. 2008;136:52-7.
2. Siniawski H, Lehmkuhl H, Weng Y, Pasic M, Yankah C, Hoffmann M, et al. Stentless aortic valves as an alternative to homografts for valve replacement in active infective endocarditis complicated by ring abscess. *Ann Thorac Surg*. 2003;75:803-8.
3. Siniawski H, Grauhan O, Hofmann M, Pasic M, Weng Y, Yankah C, et al. Aortic root abscess and secondary infective mitral valve disease: results of surgical endocarditis treatment. *Eur J Cardiothorac Surg*. 2005;27:434-40.
4. Musci M, Siniawski H, Knosalla C, Grauhan O, Weng Y, Pasic M, et al. Early and mid-term results of the Shelhigh stentless bioprosthesis in patients with active infective endocarditis. *Clin Res Cardiol*. 2006;95:247-53.
5. Musci M, Sinsiawski H, Pasic M, Weng Y, Loforte A, Kosky S, et al. Surgical therapy in patients with active infective endocarditis: seven-year single centre experience in a subgroup of 255 patients treated with the Shelhigh stentless bioprosthesis. *Eur J Cardiothorac Surg*. 2008;34:410-7.

doi:10.1016/j.jtcvs.2008.09.078

Reply to the Editor:

We thank Drs Musci, Siniawski, and Hetzer for their comments regarding our recent article entitled ''Deleterious outcome of No-React treated stentless valved conduits following aortic root replacement.''[1] We appreciate their scientific approach to the problem and congratulate the authors on their excellent results obtained in patients with active infective endocarditis.

The authors refer to 2 of their articles published in 2003[2] and 2005,[3] which both have been cited in our article. As already said, we originally believed that the Shelhigh aortic valve conduit (Shelhigh, Inc, Union, NJ) was an attractive alternative to homografts. We published our preliminary experience soon after the prosthesis was introduced and showed excellent short-term results regarding handling of the prosthesis and postoperative hemodynamics.[4] The positive experience described by the Berlin group was one of the reasons we hesitated to attribute the catastrophic outcome in several of our patients to the prosthesis itself. However, there are 2 major differences in the patient population reported by the Berlin group and ours.

First, the authors from Berlin might have overlooked the fact that, unlike in their series, the majority of our patients who received the NR2000-C prosthesis did not have endocarditis at the time of the initial operation. Our patients had subfebrile temperatures during weeks or months after elective operations for aortic root dilation, indicating that failure of the device might have mimicked destructive endocarditis. We are wondering whether Dr Hetzer's group is able to differentiate between reinfection caused by a recurrent endocarditis and failure of the device in all of their cases.

Second, most data presented by Dr Musci primarily focuses on the Shelhigh Stentless aortic valve and not on the Shelhigh aortic valved conduit. In their article published in 2005,[3] they report on 327 patients who underwent surgical intervention for endocarditis between 1996 and 2003. Only 4 (1.2%) patients in this group received the NR-2000C conduit. In the latest report,[5] with an impressive 1077 patients, the percentage of patients who received the Shelhigh NR-2000C conduit increased to 2.4%. Therefore the total number of implanted Shelhigh aortic valved conduits is 26 in Berlin compared with 115 in Berne. Moreover, the authors do not provide separate data for the NR-2000C, and previous experiences from a joint multicenter study showed that the rate of echocardiographic follow-up was very low in this institution.

The most recent case of a severe problem with a Shelhigh conduit was observed at Johns Hopkins University, and the operation was performed by Duke Cameron. The young patient